JUL 18 2000

K001359 p.1

510(k) Summary of Safety and Effectiveness

Date: April 27, 2000

Submitter: GE Marquette Medical Systems, Inc.
8200 West Tower Avenue
Milwaukee, WI 53223 USA

Contact Person: David Wahlig
Sr. Regulatory Affairs Specialist
GE Marquette Medical Systems, Inc.
Phone: (414) 362-2090
Fax: (414) 371-3736

Device: Trade Name: Dash 3000 / 4000 Patient Monitor

Common/Usual Name: Patient monitor

Classification Names:

21 CFR 868.1400	Analyzer, Gas, Carbon Dioxide, Gaseous-Phase
21 CFR 868.2375	Breathing Frequency Monitor
21 CFR 870.1025	Detector and Alarm, Arrhythmia
21 CFR 870.1100	Monitor, Blood Pressure, Indwelling
21 CFR 870.1130	Noninvasive Blood Pressure Measurement System
21 CFR 870.1100	Blood Pressure Alarm
21 CFR 870.1425	Programmable Diagnostic Computer
21 CFR 870.2340	Electrocardiograph
21 CFR 870.1435	Monitor, Cardiac Output, Thermal (Balloon Type Catheter)
21 CFR 880.2910	Monitor, Temperature (with probe)
21 CFR 870.2300	Monitor, Cardiac (Incl. Cardiotachometer & rate alarm)
21 CFR 870.2700	Oximeter, Pulse

Predicate Devices: K992929 Dash 3000 Patient Monitor

Device Description: The Dash 3000 / 4000 Patient Monitor is a device that is designed to be used to monitor, display, and print a patient's basic physiological parameters including: electrocardiography (ECG), invasive blood pressure, non-invasive blood pressure, oxygen saturation, temperature, impedance respiration, end-tidal carbon dioxide, oxygen, nitrous oxide and anesthetic agents. Other features include arrhythmia, cardiac output, cardiac and pulmonary calculations, dose calculations, PA wedge, ST analysis, and interpretive 12 lead ECG analysis (12SL). Additionally, the network interface allows for the display and transfer of network available patient data.

Intended Use: The Dash 3000 / 4000 Patient Monitoring System is intended for use under the direct supervision of a licensed healthcare practitioner. The intended use of the system is to monitor physiologic parameter data on adult, pediatric and neonatal patients. The Dash is designed as a bedside, portable, and transport monitor that can operate in all professional medical facilities and medical transport modes including but not limited to: emergency department, operating room, post anesthesia recovery, critical care, surgical intensive care, respiratory intensive care, coronary care, medical intensive care, pediatric intensive care, or neonatal intensive care areas located in hospitals, outpatient clinics, freestanding surgical centers, and other alternate care facilities, intra-hospital patient transport, inter-hospital patient transport via ground vehicles (i.e., ambulance, etc.) and fixed and rotary winged aircraft, and pre-hospital emergency response.

Physiologic data includes but is not restricted to: electrocardiogram, invasive blood pressure, noninvasive blood pressure, pulse, temperature, cardiac output, respiration, pulse oximetry, carbon dioxide, oxygen, and anesthetic agents as summarized in the operator's manual.

The Dash 3000 / 4000 Patient Monitoring System is also intended to provide physiologic data over the Unity network to clinical information systems and allow the user to access hospital data at the point-of-care.

This information can be displayed, trended, stored, and printed.

Technology: The Dash 3000 / 4000 employs the same functional technology as the predicate devices.

Test Summary: The Dash 3000 / 4000 complies with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures were applied to the development of the Dash 3000:

- Requirements specification review
- Code inspections
- Software and hardware testing
- Safety testing
- Environmental testing
- Final validation

Conclusion: The results of these measurements demonstrated that the Dash 3000 / 4000 is as safe, as effective, and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 2000

David Wahlig
Corporate Regulatory Affairs
GE Marquette Medical Systems, Inc.
8200 W. Tower Ave.
Milwaukee, WI 53223

Re: K001359
Dash 3000/4000 Patient Monitor
Regulatory Class: III (Three)
Product Code: 74 DSI
Dated: April 27, 2000
Received: April 28, 2000

Dear Mr. Wahlig:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket

notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

510(k) Number (if known): K001359 510(k) filed on April 27, 2000

Device Name: Dash 3000 / 4000 Patient Monitor

Indications For Use:

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for Mark N Melkerson

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K001359

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)